CLAIMS

What is claimed is:

1. A method for quantitatively measuring the amount of an analyte of interest in a fluid sample, comprising:

a) providing a membrane strip comprising an application point, a contact region, a sample capture zone and a control capture zone, wherein the contact region is between the application point and the sample capture zone and the sample capture zone is between the contact region and the control capture zone;

b) contacting the application point of the membrane strip with the fluid sample to be assayed for the analyte of interest;

c) maintaining the membrane strip under conditions which allow fluid to transport analyte of interest in the fluid sample by capillary action through the strip to and through the contact region, the contact region having a population of analyte-binding particles immobilized therein, wherein the analyte-binding particles are coated with an analyte-binding agent;

d) further maintaining the membrane strip under conditions which allow analyte of interest, if present in the sample, to bind to analyte-binding particles, thereby generating contacted analyte-binding particles; allow the fluid in the sample to mobilize and transport contacted analyte-binding particles by capillary action through the strip to and through the sample capture zone, the sample capture zone having a sample capture reagent immobilized thereon; and allow contacted analyte-binding particles to bind to the sample capture reagent;

e) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport contacted analyte-binding particles by

capillary action through the strip to and through the control capture zone, the control capture zone having a control capture reagent immobilized thereon; and allow contacted analyte-binding particles to bind to the control capture reagent;

f) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport any contacted analyte-binding particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone;.

g) determining the amount of contacted analyte-binding particles in the sample capture zone and the amount of contacted analyte-binding particles in the control capture zone;

h) determining a corrected analyte-binding particle amount from the amount of analyte-binding particles in the sample capture zone and the amount of analyte-binding particles in the control capture zone,

wherein the amount of analyte of interest in the fluid sample is directly related to the corrected analyte-binding particle amount.

2. The method of Claim 1, wherein the corrected analyte-binding particle amount is determined as a ratio of the amount of analyte-binding particles in the sample capture zone, to the amount of analyte-binding particles in the control capture zone.

3. The method of Claim 1, wherein the corrected analyte-binding particle amount is determined as a ratio of the amount of analyte-binding particles in the sample capture zone, to the sum of the amount of analyte-binding particles in the control capture zone and the amount of analyte-binding particles in the sample capture zone.

4. The method of Claim 1, wherein the membrane strip is made of cellulose nitrate or glass fiber.

5. The method of Claim 1, wherein the particles are latex beads.

6. The method of Claim 1, wherein the particles are labeled.

7. The method of Claim 6, wherein the label is selected from the group consisting of: colorimetric, fluorescent, phosphorescent, luminescent, chemiluminescent, and enzyme-linked molecule.

8. The method of Claim 1, wherein the analyte and the analyte-binding agent are members of a binding pair, and one member of the binding pair is selected from the group consisting of: a protein, a hormone, an enzyme, a glycoprotein, a peptide, a small molecule, a polysaccharide, a lectin, an antibody, an antibody fragment, a nucleic acid, a drug, a drug conjugate, a toxin, a virus, a virus particle, a portion of a cell wall, a hapten, and a receptor.

9. The method of Claim 1, wherein the analyte-binding agent is selected from the group consisting of: an antibody; an antibody fragment; a hapten; a drug conjugate; and a receptor.

10. The method of Claim 9, wherein the analyte-binding agent is an antibody.

11. The method of Claim 10, wherein the sample capture reagent is an antibody selected from the group consisting of: an antibody directed against the same epitope as the antibody on the analyte-binding particles, and an antibody directed against a different epitope as the antibody on the analyte-binding particles.

12. The method of Claim 10, wherein the control capture reagent is an anti-immunoglobulin antibody.

13. The method of Claim 1, wherein the test sample is selected from the group consisting of: whole blood, plasma, serum, urine, cerebrospinal fluid, saliva, semen, vitreous fluid, or synovial fluid.

14. The method of Claim 1, wherein the analyte of interest is selected from the group consisting of: myoglobin, CK-MB, troponin I, and PSA.

15. The method of Claim 1, wherein in step (f) the fluid in the sample transports any contacted analyte-binding particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone into a wicking pad.

16. A method for measuring the amount of an analyte of interest in a fluid sample, comprising:

a) providing a membrane strip comprising an application point, a contact region, a sample capture zone and a control capture zone, wherein the contact region is between the application point and the sample capture zone and the sample capture zone is between the contact region and the control capture zone;

b) contacting the sample capture zone of the membrane strip with the fluid sample, the sample capture zone having a sample capture reagent immobilized thereon, and maintaining the membrane strip under conditions which allow analyte of interest, if present in the sample, to bind to the sample capture reagent in the sample capture zone, thereby generating arrested analyte;

c) contacting the application point of the membrane strip with a buffer;

d) maintaining the membrane strip under conditions which allow the buffer to mobilize and transport a population of analyte-binding particles immobilized in the contact region by capillary action to and through the sample capture zone, wherein the analyte-binding particles are coated with an antibody to the analyte; and allow the arrested analyte to interact with analyte-binding particles, thereby generating arrested analyte-particle complexes;

e) further maintaining the membrane strip under conditions which allow the buffer to transport analyte-binding particles by capillary action to and through the control capture zone, the control capture zone having a control capture reagent immobilized thereon; and allow analyte-binding particles to bind to the control capture reagent;

f) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport any analyte-binding particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone;

g) determining the amount of analyte-binding particles in the sample capture zone and the amount of analyte-binding particles in the in the control capture zone; and

h) determining a corrected analyte-binding particle amount from the amount of analyte-binding particles in the sample capture zone and the amount of analyte-binding particles in the control capture zone,

wherein the amount of analyte of interest in the fluid sample is directly related to the corrected analyte-binding particle amount.

17. The method of Claim 16, wherein the corrected analyte-binding particle amount is determined as a ratio of the amount of analyte-binding particles in the sample capture zone, to the amount of analyte-binding particles in the control capture zone.

18. The method of Claim 16, wherein the corrected analyte-binding particle amount is determined as a ratio of the amount of analyte-binding particles in the sample capture zone, to the sum of the amount of analyte-binding particles in the control capture zone and the amount of analyte-binding particles in the sample capture zone.

19. A method for quantitatively measuring the amount of an analyte of interest in a fluid sample, comprising:

a) providing a membrane strip comprising an application point, a contact region, a sample capture zone and a control capture zone, wherein the contact region is between the application point and the sample capture zone and the sample capture zone is between the contact region and the control capture zone;

b) contacting the application point of the membrane strip with the fluid sample to be assayed for the analyte of interest;

c) maintaining the membrane strip under conditions which allow fluid to transport analyte of interest in the fluid sample by capillary action through the strip to and through the contact region, the contact region having a population of analyte-coated particles immobilized therein, wherein the analyte-coated particles are coated with analyte of interest;

d) further maintaining the membrane strip under conditions which allow the fluid in the sample to mobilize and transport analyte-coated particles by capillary action through the strip to and through the sample capture zone, the sample capture zone having a sample capture reagent immobilized thereon; and allow analyte-coated particles to bind to the sample capture reagent;

e) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport analyte-coated particles by capillary action through the strip to and through the control capture zone, the

control capture zone having a control capture reagent immobilized thereon; and allow analyte-coated particles to bind to the control capture reagent;

f) further maintaining the membrane strip under conditions which allow the fluid in the sample to transport any analyte-coated particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone;

g) determining the amount of analyte-coated particles in the sample capture zone and the amount of analyte-coated particles in the control capture zone;

h) determining a corrected analyte-coated particle amount from the amount of analyte-coated particles in the sample capture zone and the amount of analyte-coated particles in the control capture zone,

wherein the amount of analyte of interest in the fluid sample is inversely related to the corrected analyte-coated particle amount.

20. The method of Claim 19, wherein the corrected analyte-coated particle amount is determined as a ratio of the amount of analyte-coated particles in the sample capture zone, to the amount of analyte-coated particles in the control capture zone.

21. The method of Claim 19, wherein the corrected analyte-coated particle amount is determined as a ratio of the amount of analyte-coated particles in the sample capture zone, to the sum of the amount of analyte-coated particles in the control capture zone and the amount of analyte-coated particles in the sample capture zone.

22. The method of Claim 19, wherein the membrane strip is made of cellulose nitrate or glass fiber.

23. The method of Claim 19, wherein the particles are latex beads.

24. The method of Claim 19, wherein the particles are labeled.

25. The method of Claim 24, wherein the label is selected from the group consisting of: colorimetric, fluorescent, phosphorescent, luminescent, chemiluminescent, and enzyme-linked molecule.

26. The method of Claim 19, wherein the analyte and the analyte-binding agent are members of a binding pair, and one member of the binding pair is selected from the group consisting of: a protein, a hormone, an enzyme, a glycoprotein, a peptide, a small molecule, a polysaccharide, a lectin, an antibody, an antibody fragment, a nucleic acid, a drug, a drug conjugate, a toxin, a virus, a virus particle, a portion of a cell wall, a hapten, and a receptor.

27. The method of Claim 19, wherein the analyte-binding agent is selected from the group consisting of: an antibody; an antibody fragment; a hapten; a drug conjugate; and a receptor.

28. The method of Claim 27, wherein the analyte-binding agent is an antibody.

29. The method of Claim 28, wherein the control capture reagent is an antibody.

30. The method of Claim 19, wherein the test sample is selected from the group consisting of: whole blood, plasma, serum, urine, cerebrospinal fluid, saliva, semen, vitreous fluid, or synovial fluid.

31. The method of Claim 19, wherein the analyte of interest is selected from the group consisting of: digoxin, theophylline, hormone T-3, hormone T-4, LSD, THC, and a barbiturate.

32. The method of Claim 19, wherein in step (f) the fluid in the sample transports any analyte-coated particles not bound to the sample capture reagent or to the control capture reagent by capillary action beyond the control capture zone into a wicking pad.